



# EU system of tobacco traceability



**DG SANTE, European Commission**  
**Cross-border health care and tobacco control**

**Taipei**  
 **September 2019**

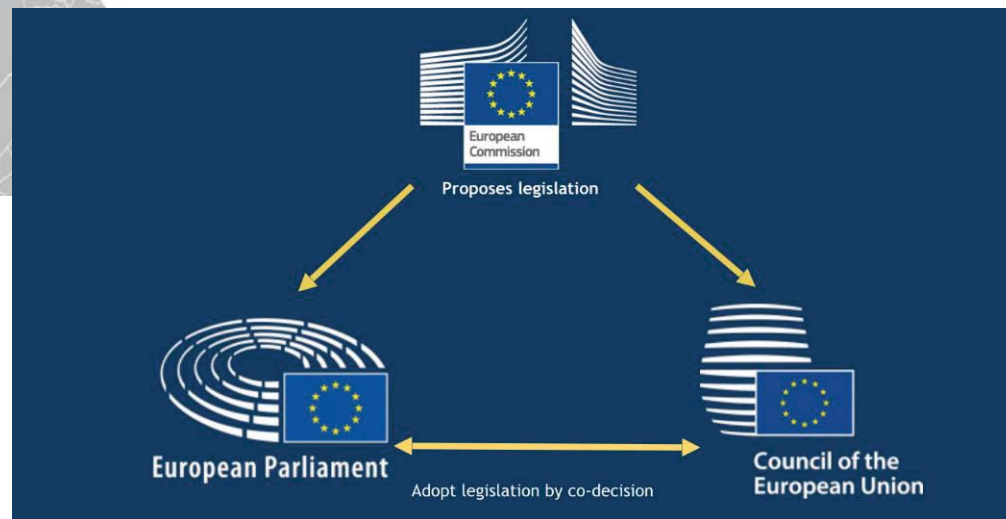
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- Introduction – EU context
- Legislative response to the problem of illicit trade
- Legal basis of the EU system of tobacco traceability
- General architecture and the key entities
- Product marking and structure of unique identifiers
- Recording rules
- Public control over the system
- Cost-benefit of the system
- Final remarks



# European Union



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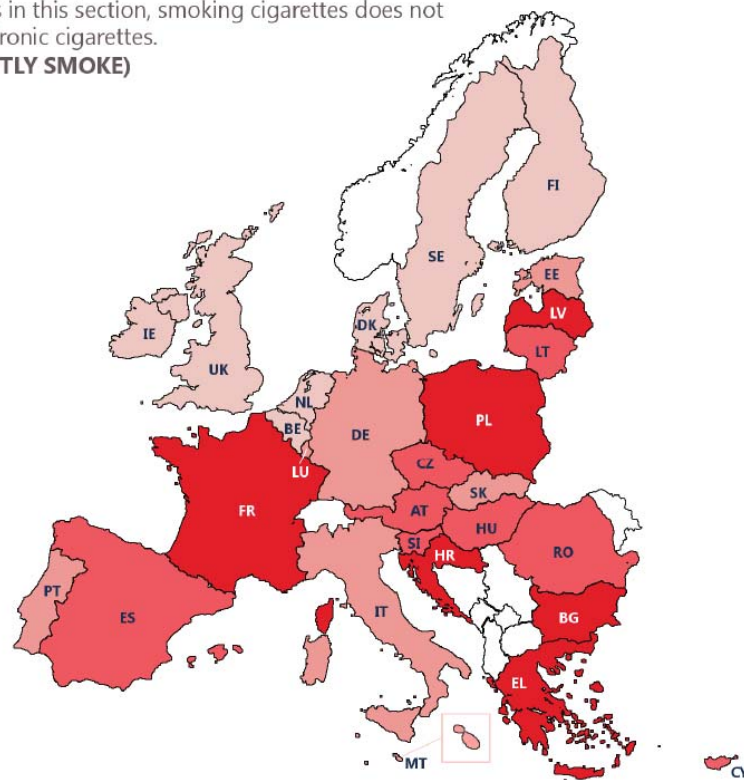
# EU market for tobacco products



**QB1** Regarding smoking cigarettes, cigars, cigarillos or a pipe, which of the following applies to you? In this question and the following questions in this section, smoking cigarettes does not include use of electronic cigarettes.  
(% - YOU CURRENTLY SMOKE)

**Map Legend**

- 30 - 100
- 27 - 29
- 21 - 26
- 0 - 20



EL	37
BG	36
FR	36
HR	35
LV	32
PL	30
CZ	29
LT	29
CY	28
AT	28
RO	28
SI	28
ES	28
HU	27
PT	26
EU28	26
SK	26
DE	25
MT	24
IT	24
EE	23
LU	21
FI	20
BE	19
DK	19
IE	19
NL	19
UK	17
SE	7

## Releases for consumption of cigarettes in the EU

Year	In bn sticks
2002	778
2007	722
2012	553
2017	471

Source: EC DG TAXUD

Source: EB 2017

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# Nature of illicit trade in the EU



- Volume: 10-11% of the overall market; tax losses: €10bn+;
- Important public health implications;
- Composition of illicit market changes: contraband from major international products, cheap whites and counterfeits, domestic illicit manufacture;
- Main countries of provenance for smuggled tobacco in the EU: China, UAE, Vietnam, Malaysia, Russia, Singapore, Belarus, Ukraine;
- Points of entry: EU Eastern border, Eastern Mediterranean, Western Balkans;
- Fuels the shadow economy;
- Often domain of organised criminal groups;
- Worldwide, complex problem -> needs to be addressed in a comprehensive way, both geographically and in terms of rules, resources and products.



# Factors contributing to illicit trade



- High incentives and substantial loopholes
- Insufficient supply chain control measures
- Enforcement challenges
- Low disincentives

(COM Communication: stepping up the fight against cigarette smuggling and other forms of illicit trade in tobacco products)





## EU response

- Articles 15 and 16 of Tobacco Products Directive 2014/40/EU establish:
  - **EU-wide system for tracking and tracing (from the manufacturer to the last point before the retail outlet)**
  - **Security features**

## International response

- FCTC Protocol (Article 8, on traceability)



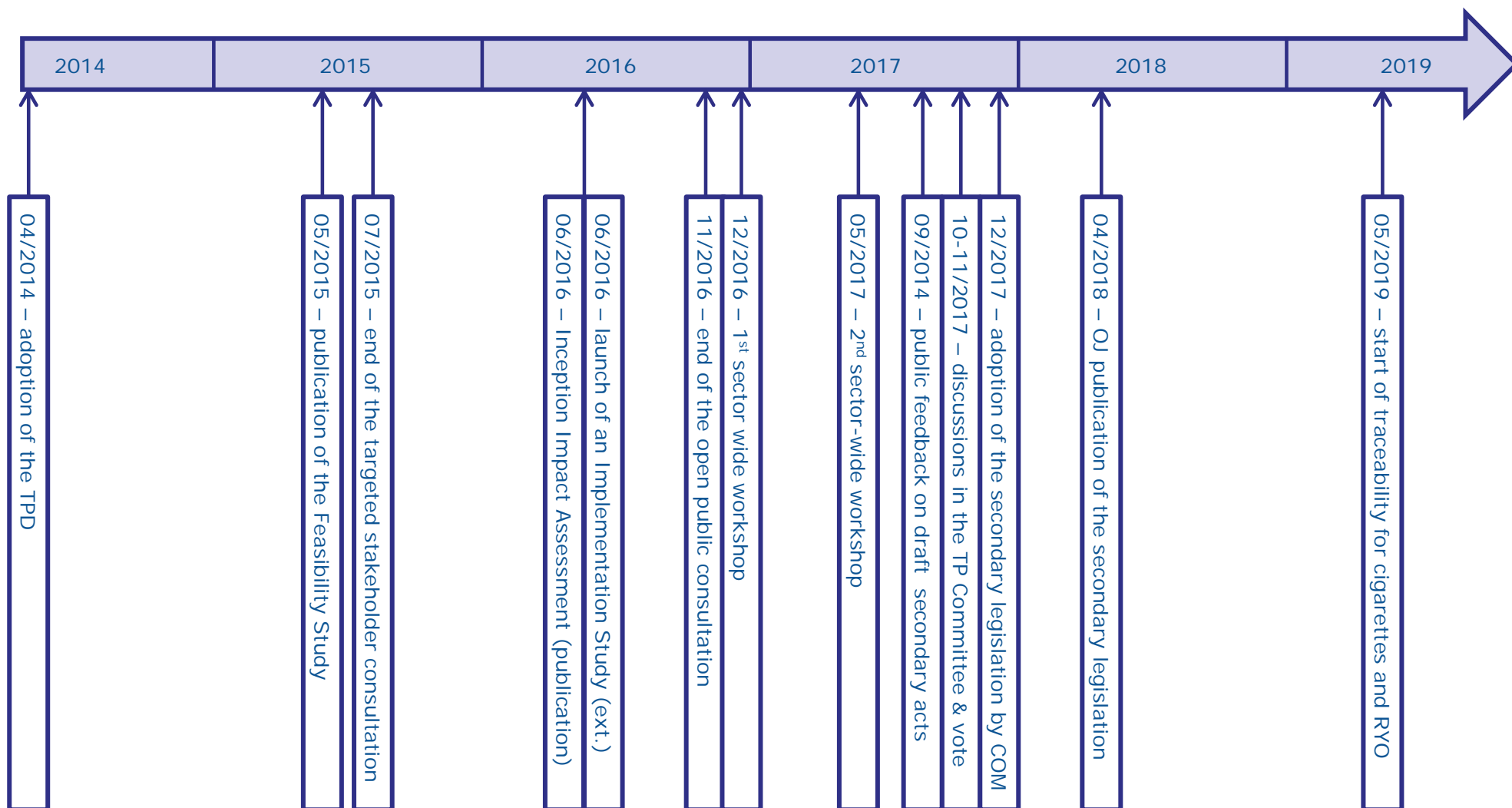


- Articles 15 of the Tobacco Products Directive 2014/40/EU (TPD) provides for an EU-wide system of traceability for tobacco products to address the issue of illicit trade. It introduces the tracking and tracing system with a unique identifier (UI) at the level of a unit packet of tobacco products;
- International Treaties: Article 15 of Framework Convention on Tobacco Control (FCTC) and Article 8 of the FCTC Protocol requiring the Parties to establish a tracking and tracing system.
- Secondary legislation: Commission Implementing Regulation (EU) 2018/574 (incl. Annex I and II) and Commission Delegated Regulation (EU) 2018/573.
- *Implementation deadline under the TPD: 20/05/2019 (for cigarettes and RYO) and 20/05/2024 (for other tobacco products).*





# Timeline



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# Key requirements



Art. 15(5) TPD: Member States shall ensure that all economic operators involved in the trade of tobacco products, **from the manufacturer to the last economic operator before the first retail outlet**, record the **entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession**. This obligation may be complied with by the marking and recording of aggregated packaging such as cartons, mastercases or pallets, provided that the tracking and tracing of all unit packets remains possible.

Art. 15(1) TPD → Art. 6 CIR:

1. Manufacturers and importers shall mark each unit packet **manufactured or imported in the Union** with a unique identifier ('unit level UI') compliant with Article 8.

2. In the case of tobacco products that are manufactured outside the Union, the unit level UI shall be applied on the unit packet **before the tobacco product is imported in the Union**.



# Key characteristics

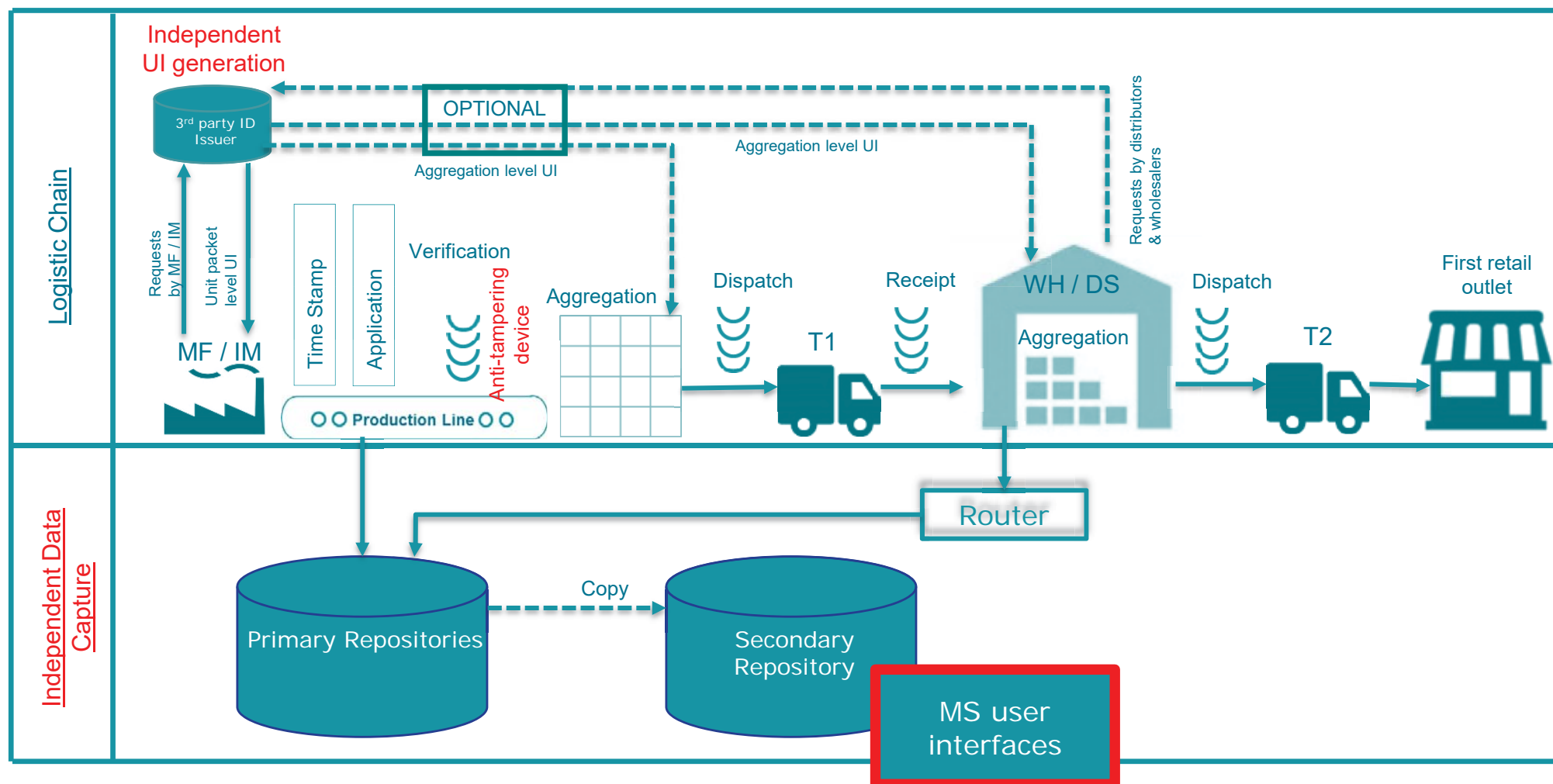


EU-wide system for traceability of tobacco products requires that all unit packets of tobacco products produced in, destined for or placed on the EU market:

- Have to be marked with a unique identifier;
- Their movements need to be recorded throughout the entire supply chain;
- Related information needs to be made available to authorities for enforcement purposes.



# General architecture



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# Key entities



- ID issuers
  - **key responsibility: generation and issuing UIs and registration of economic operators, facilities and machines**
  - **appointed by Member States on a national basis;**
  - **maximum number: as many as Member States.**
- Primary repositories
  - **key responsibilities: storage of traceability data on products of a given manufacturer/importer;**
  - **contracted by individual manufacturers/importers and approved by the Commission;**
  - **maximum number: as many as manufacturers/importers;**
- Secondary repository
  - **key responsibilities: central router, central copy of traceability data, access interfaces for authorities, common data dictionary and connectivity specifications;**
  - **selected among the primary repositories by the Commission;**
  - **maximum number: one.**



# Independence criteria



Pursuant to Art. 35 CIR, ID issuers, providers of repository services and anti-tampering devices as well as, where applicable, their subcontractors shall be independent and exercise their functions impartially.

The following criteria are used to assess independence:

- independence from the tobacco industry in terms of legal form, organisation and decision making;
- independence from the tobacco industry in financial terms;
- absence of conflicts of interests with the tobacco industry of the persons in the management positions.

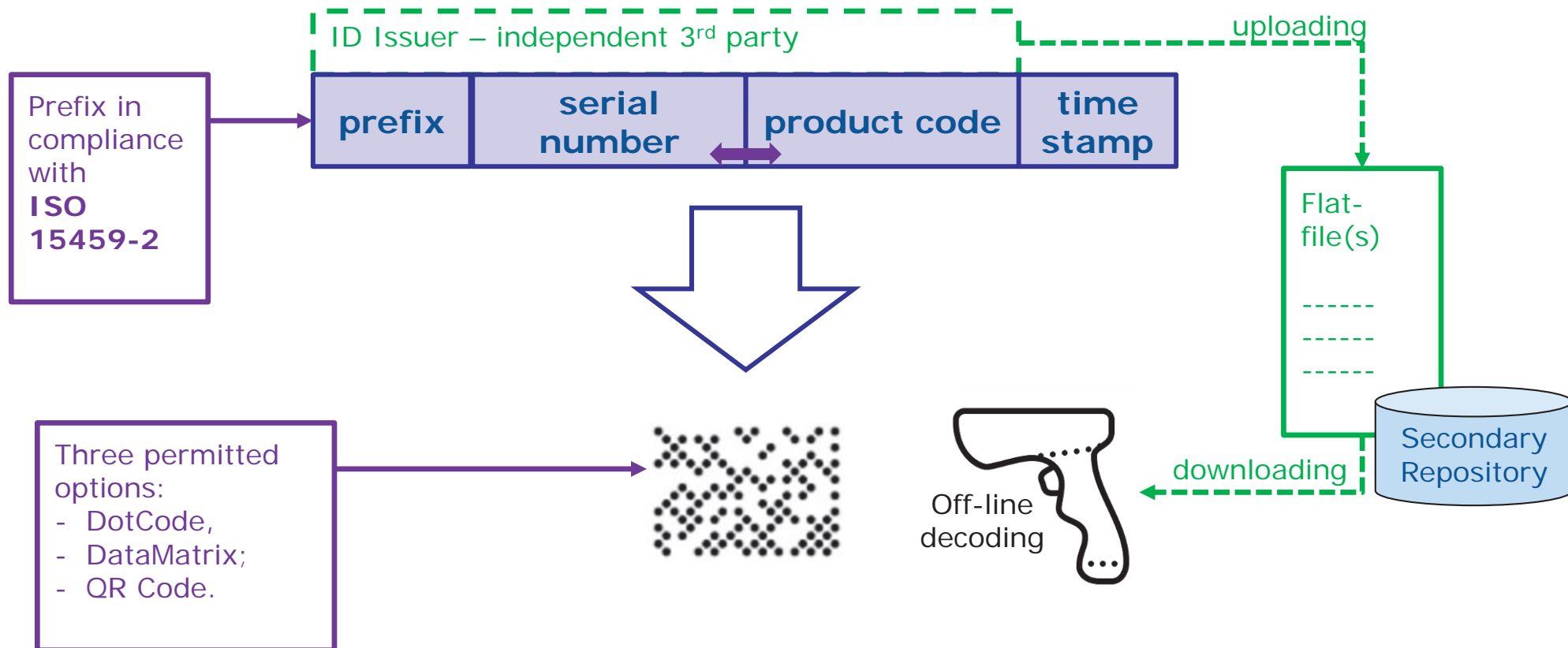


# Unit pack level UIs



*Art. 15(1) → uniqueness*

*Art. 15(2) (a) to (h) → data items to be determined*



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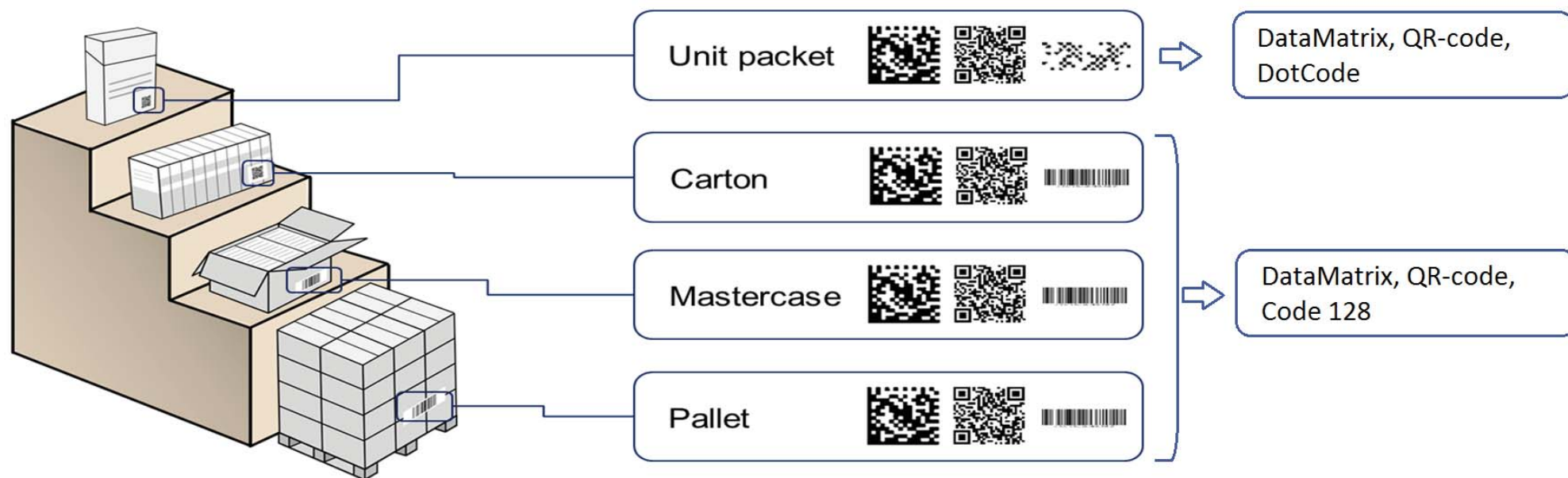
- Art. 8(1) CIR provides that a unit level UI shall not exceed 50 characters and be composed of the following data elements:
  - the **ID issuer identification** (in line with ISO 15459);
  - **Serial number**;
  - **Product code** allowing for determining:
    - the place of manufacturing;
    - the manufacturing facility;
    - the machine used to manufacture the tobacco products;
    - the product description;
    - the intended market of retail sale;
    - the intended shipment route;
    - where applicable, the importer into the Union;
  - **Time stamp.**
- Art. 8(4) CIR requires that unit level UIs shall not include any other data elements.

Art.  
15.1

Art. 15.2 & 3. of the TPD



# Marking with UIs



- + a human-readable code that enables electronic access to the information related to the unique identifiers stored in the repositories system.

# UI example



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# UIs – main steps for the industry



- Pre-registration in the system to obtain codes for economic operator, facility & machine;
- Request for UIs from competent ID issuer;
  - Delivery methods: electronically (default), physically (at discretion of Member States);
  - 6 months validity of UIs (from date of receipt to application);
- Marking of unit packets with UIs at the production line;
- Verification as to correct application/readability of UIs;
  - Anti-tampering devices;
- Further reporting on all logistic and financial operations concerning the marked products on the basis of UIs.

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# Request for UIs (1/3)



## 2.1. Request for unit level UIs

Item #	Field	Comments	Data Type	Cardinality	Priority	Values
	Message_Type	Identification of message type	Text	S	M	2-1
	EO_ID	Economic operator identifier code of the submitting entity (either EU manufacturer or EU importer)	EOID	S	M	
	F_ID	Facility identifier code	FID	S	M	
	Process_Type	Indication if the production process involves machinery	Boolean	S	M	0 – No (only for fully hand made products) 1 – Yes
	M_ID	Machine identifier code	MID	S	M, if Process_Type = 1	
	P_Type	Type of tobacco product	Integer	S	M	1 — Cigarette 2 — Cigar 3 — Cigarillo 4 — Roll your own tobacco 5 — Pipe tobacco 6 — Waterpipe tobacco 7 — Oral tobacco 8 — Nasal tobacco 9 — Chewing tobacco 10 — Novel tobacco product 11 — Other (product placed on the market before 19 May 2014, not covered by categories 1-9)

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# Request for UIs (2/3)



Item #	Field	Comments	Data Type	Cardinality	Priority	Values
	P_OtherType	Description of other type of tobacco product	Text	S	M, if P_Type = 11	
	P_CN	Combined Nomenclature (CN) code	Text	S	O	
	P_Brand	Brand of tobacco product	Text	S	M	
	P_weight	Average gross weight of unit packet, including packaging, in grams with 0,1 gram accuracy	Decimal	S	M	
	TP_ID	Tobacco product identifier used in the EU-CEG system	TPID	S	M, if Intended_Market is an EU country	
	TP_PN	Tobacco product number used in the EU-CEG system	PN	S	M, if Intended_Market is an EU country	
	Intended_Market	Intended country of retail sale	Country	S	M	

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# Request for UIs (3/3)



	Intended_Route1	Indication if the product is intended to be moved across country borders with terrestrial/water/air transport	Boolean	S	M	0 – No 1 – Yes
	Intended_Route2	The first country of terrestrial/water/air transport after the product leaves the Member State of manufacturing or the Member State of importation established on the basis of a check point on the land border, next seaport or next airport respectively	Country	S	M, if Intended_Route1 = 1	
	Import	Indication if the product is imported into the EU	Boolean	S	M	0 – No 1 – Yes
	Req_Quantity	Requested quantity of unit packet level UIs	Integer	S	M	

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## Recording of information on product movements (Art. 32 CIR)

- Required for: application of UI, dispatch, arrival, trans-loading
- Special cases: vending machines, vending vans
- Disaggregation of aggregated level UI intended for reuse (self-generated UIs)

## Transmission of information on product movements (Art. 32 CIR)

- Transmission of information to primary repository (for MF/IMP) or via router to secondary repository (for all other EOs)
- Stolen/ destroyed products require deactivation request
- Correct transmission = positive acknowledgment from repository







## Recording of information on transactions (Art. 33 CIR)

- Required for: issuing of order number/invoice, payment receipt
  - Once the relevant event occurred and can be linked to respective UIs.
- Responsibility to transmit information lies with the vendor
- Transmission of information to primary repository (for MF/IMP) or via router to secondary repository (for all other EOs)
- Correct transmission = positive acknowledgment from repository







## Within **3 hours from the** occurrence of the event

- Required for the following events:
  - Application of unit level and aggregated level UIs
  - Arrival of tobacco products at a facility
  - Disaggregation (where UI is intended for reuse)
  - Delivery to multiple retail outlets via a vending van
  - Transactional events
- Applicable only from 20 May 2028; until then **24h rule** applies.
- General **derogation** (i.e. 24h rule applies permanently) for
  - Undertakings/group of undertakings which handle <120mil UI per year
  - Undertakings/group of undertakings that meet the definition of SME

## Within **24 hours prior to** the occurrence of the event

- Required for the following events:
  - Dispatch of tobacco products from a facility
  - Trans-loading





Public control provided by the combination of several measures:

- Independent issuers of unique identifiers;
- Independent storage of traceability data;
- Strict set of rules detailing the independence criteria;
- Presence of a central dataset;
- Message and data dictionaries;
- Specific and strict timeframe for reporting, including prior notification of products in move, combined with live monitoring by authorities;
- Pre-registration and coding of all economic operators, facilities (including retail outlets) and production machines;
- Regular audits.



# Cost-benefit calculations



## Cost implications per preferred policy options:

Preferred policy options	Annualised cost (EUR million)	Cost per unit pack (EUR)
1a/3: Mixed solution (industry and third party)	43.0	0.001451
1b/1: Near real time reports	48.7	0.001642
1c/3: Combined model	10.5	0.000353
2/4: Limited data carriers per level (and optional)	37.6	0.001268
<b>Total (Article 15 TPD)</b>	139.7	0.004714
3/2: Printing or affixing or a combination of printing and affixing	14.9	0.000502
<b>Total (Articles 15 &amp; 16 TPD)</b>	<b>154.6</b>	

## Distribution of costs and benefits per stakeholder group:

Affected stakeholders	Social benefits	Economic benefits	Economic costs
Competent authorities	219	2029	4.1
Economic operators, incl.:	n/a	59.1	150.6
- manufacturers/importers		45.4	78.9
- distributors/wholesalers		5.8	71.6
- retailers		7.9	n/a
General public	1497	n/a	n/a
<b>Total (EUR)</b>	<b>1716</b>	<b>2088</b>	<b>155</b>

*Annual costs and benefits per stakeholder group (in EUR million)*

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## The EU system:

- is in full compliance with the FCTC Protocol;
- is a good fit for the needs of any other FCTC Party with well-developed IT infrastructure;
- has all the core rules designed by the public authorities (not a private operator with vested interests);
- involves multiple public authorities looking at the same data in real time (peer pressure); use of AI;
- is a system in which verification of independence is a continuous exercise;
- is designed to accommodate multiple providers and hence provides for a higher level of independence; any potential collusion with TI is much less likely to occur.





**For more information, please consult:**

**[https://ec.europa.eu/health/tobacco/tracking\\_tracing\\_system\\_en](https://ec.europa.eu/health/tobacco/tracking_tracing_system_en)**

